Exhibit F

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IN RE:	:SUPERIOR COURT OF
PELVIC MESH/GYNECARE	:NEW JERSEY
LITIGATION	:LAW DIVISION -
	:ATLANTIC COUNTY
	:
	:MASTER CASE 6341-10
	:
	:CASE NO. 291 CT

CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

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September 12, 2012

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Volume I of the transcript of the Deposition of CHARLOTTE OWENS, M.D., called for Videotaped Examination in the above-captioned matter, said deposition taken pursuant to Superior Court Rules of Practice and Procedure, by and before JoRita B. Meyer, a Certified Realtime Reporter, Registered Merit Reporter, and Certified Court Reporter for the State of Georgia, at the offices of Troutman Sanders, 600 Peachtree Street Northeast, Atlanta, Georgia, commencing at 9:39 a.m.

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purpose of the IFU?

A. The IFU is a document to provide some general and some specific information to the physician about the use of our product.

Q. Did you understand that the IFU is considered under FDA regulations to be the primary label for the medical device, in this case, the PROLIFT?

A. Yes.

Q. And you understood this would be the primary source of information that surgeons would look to to get information with regard to the safety and efficacy and potential risks of using the PROLIFT with patients, correct?

A. When you say "primary," what do you mean by "primary"?

Q. Meaning this would be the first -- well, rephrase.

When I say "primary," I say that if -- if there was anything that a surgeon would look at, it would be this, this would be the first thing that they would look to?

A. I don't know if it's the first thing that they would look to, because this would have been part of our entire professional

education package; so this would be one of the things that they would look to, yes.

Q. Do you understand the significance under FDA regulations of the IFU being the primary label for the PROLIFT?

A. I understand the FDA regulations around the document. I also understand the way that physicians are trained and operate.

MR. SLATER: Move to strike from "I also" forward.

BY MR. SLATER:

Q. What's your understanding as to the significance of the IFU being the primary label for the PROLIFT from FDA regulatory standpoint?

A. That the agency sees this as the document that they review as a part of the packaging for our materials. So it should contain the relevant indications, description, and -- and other pertinent information as prescribed by the regulations.

Q. That would also include all necessary contraindications, warnings and precautions, and adverse reactions, correct?

A. It would include warnings, precautions, contraindications, adverse

reactions, sterility, disposal, storage, et cetera.

Q. You have understood that all of the information in the IFU needed to be accurate, correct?

A. Yes.

Q. You understood that physicians were going to rely on the IFU in making decisions about whether or not to use the PROLIFT in treating patients, correct?

MR. BROWN: Objection.

THE WITNESS: Physicians will not rely solely on the IFU for making their decisions. Physicians will use the IFU to help inform them, but they will also use other information.

BY MR. SLATER:

Q. You understood physicians would rely, at least in part, on the PROLIFT IFU in making decisions about whether they wanted to use that product, that medical device, that system, in their patients, correct?

MR. BROWN: Objection.

THE WITNESS: Physicians will use this document and other documents to

decide if they want to learn more about the system, and ultimately will use their training, education, and experience, plus this document, to decide if they want to use it.

BY MR. SLATER:

Q. Did you understand that it was necessary to clearly and unambiguously communicate all necessary contraindications, warnings and precautions, and adverse reactions to physicians through the IFU?

A. I understand the document should be clear and unambiguous, yes.

Q. Did you understand that it was necessary for Gynecare, to the extent that a risk was understood to exist with the PROLIFT, to communicate it in the IFU as opposed to assuming that surgeons would figure out that risk on their own?

A. I don't think you're giving surgeons enough credit. Surgeons don't have to figure out the complications of an area that they operate. Surgeons are trained to know the complications of the area in which they operate.

BY MR. SLATER:

Q. Does it mean too much tension?

A. It's not that simple.

Q. How would a surgeon doing the procedure be able to objectively verify, based on an objective standard, that they had placed or not placed the mesh with excessive tension?

A. They would be able to look at the repair after surgery and see if it looks relaxed or see if it looks like it's under tension.

Q. So that's how they would do it?

A. That's generally how it was done.

Q. Did you ever perform the PROLIFT procedure?

A. On the cadavers, yes. In live people, because I was not practicing during my tenure at Ethicon, no.

Q. Did you ever on your own, without any other surgeon performing the procedure -- did you ever place Gynemesh in a human's body?

A. No.

Q. Look at the adverse reactions, please. It was your understanding that you needed to list each of the adverse reactions

that were known to you in Medical Affairs in this section, correct?

A. Yes.

Q. And you understood that if you failed to list adverse reactions that you were aware of, that that would render that warning deficient to some extent, correct?

A. Deficient?

MR. BROWN: Objection.

THE WITNESS: I would say that we listed the adverse reactions that we knew were adequate and sufficient for this document.

BY MR. SLATER:

Q. Well, you just said a moment ago you agreed with me that you understood you were supposed to list each of the adverse reactions that you in Medical Affairs knew existed at the time of launch, correct?

A. We listed the adverse events that we knew to be directly related to the information that we had at this time.

Q. Okay. Were there risks -- well, rephrase.

You see where it says, at the end of

A. Correct.

Q. And it says the potential effect of that is damage to the cannula and the potential hazard what could occur would be tissue damage, correct?

A. Correct.

Q. And the potential harm that could result here is described as bleeding, correct?

A. Correct.

Q. And you understood that through your review of this -- rephrase.

And you understood that it was required that you capture all of the different failure modes, all the things that could go wrong in the procedure, even if the doctor was properly trained and following the proper procedure, and the effects of those failure modes, the hazards that could occur, and the resulting harms, and you were supposed to capture all of them, correct?

A. Yes, all that we could conceive of, yes.

Q. Now, one of the things that could happen is during the passage of the guides, is the pudendal nerve could be injured, correct?

specifically mentioned in the document.
BY MR. SLATER:
Q. And therefore, none of them are specifically scored, correct?
A. They would have been included in things other than the terms that you mentioned.
Q. As the document appears and as it was specifically and carefully written by quality engineering, with your approval, those items do not appear and are not specifically scored, correct?
A. Those items are not specifically mentioned, no.
Q. All right. Now let's look at the dFMEA, which is Exhibit 629. You understood the purpose of the dFMEA, correct?
A. Yes.
Q. That's the Design Failure Modes and Effects Analysis, correct?
A. Yes.
Q. And what was the purpose of this analysis?
A. To review the potential risk associated with the design of the product.
Q. And when you say "associated with the

design of the product," that means that when the product is in a woman's body and the product was manufactured completely consistent with the specifications, these are the things that could go wrong and harm a patient, correct?

A. Correct.

Q. Let's look now at this dFMEA, and let's look at page -- looking at the Bates number 03573, the actual chart and grid.

And it indicates that you were one of the individuals who provided input as medical director, correct?

A. Yes.

Q. And again, as with the aFMEA, you had to sign off on the dFMEA in order for this gate to be surpassed so the product could move closer to Product Release Authorization and to be marketed to be put in women's bodies, correct?

A. Correct.

Q. And what this does is, in the chart, is the different components of the PROLIFT kit are each evaluated in terms of what harms they could cause if they were to fail, correct?